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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,360	02/06/2004	Dietmar W. Humacher	NAA 0021 PA/41049.23	5378

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DINSMORE & SHOHL LLP
Suite 500
One Dayton Centre
Dayton, OH 45402-2050

EXAMINER

REDDING, DAVID A

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/774,360

Applicant(s)

HUTMACHER ET AL.

Examiner

David A Redding

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1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17 is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 7, 11, 14, 15, 18, 19, 21 and 22 is/are rejected.
- 7) ☒ Claim(s) 4, 5, 8-10, 12, 13, 16 and 20 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent 5,523,228 (Ingram et al.).

Claims 21 and 22 constitute Product-by-process claims.

The courts have held, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

The Ingram et al patent discloses the method for producing three dimension cell cultures (col.7; claim 7). Table 1 provides a list of the three dimensional cell lines.

Though the method for culturing the cells are different from the process claimed, the disclosed three dimensional cells are considered to anticipate the claimed cell cultures.

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Claims 1-3,18,19, are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/32270 (Crawford).

The Crawford reference discloses a device which provides for dual axis rotation of a chamber (4). The device includes a gas or liquid feed (12,13) into the chamber during rotation. The chamber (4) is described as a two-part mold. The chamber is considered to be liquid tight and capable of containing cells and a culture medium since the chamber is disclosed as holding a liquid reactant (page 2, line 13-15). The reference does not describe the motors for providing the dual axis rotation. However, from the description of figure1 it is clear that to function as described the device would inherently include a motor for spinning the support arm (3) about the horizontal axis (3) and another motor for rotating the chamber (4) about the vertical axis (6), more than likely positioned below the chamber (4). The device also includes a fluidly sealed passage (12,13,15,19) for providing a gas or liquid. The reference also discloses that the rotation about the dual axis are independent and variable (page 3, lines 14-17) and as described would inherently comprise a controller for providing the described function.

Claims 1,2,6,7,11,15, 18, are rejected under 35 U.S.C. 102(b) as being anticipated by US patent 5,501,522 (Tung).

The tung patent discloses a device for providing dual axis rotation of a chamber (50) (abstract; col.1, lines 22-29; col.2.thru 3, lines 64-6). The device is capable of providing varying speed of the motors so as both the primary and secondary rotation of the container can be controlled to a fine degree (col. 3, lines 6-9). The device would inherently include a controller for providing the "fine degree" rotation of the chamber.

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The device comprises two motors (20, 60) engaged with gear mechanisms (30, 40).

The reactant chamber (55) comprises a sealing lid (54) and is considered to be capable of containing cell and medium. The reference also discloses controlling the temperature and pressure in the chamber (55) (col.1, lines 32-36) and thus inherently would include a sensor for monitoring the temperature in the chamber.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,501,522 (Tung) in view of US patent 5,148,090 (Oku et al.).

The Tung patent is silent as to the types of motors (30,60) for providing the rotation. The Oku et al. patent discloses a servo motor for providing rotation to a shaft (figure 7). Accordingly it would have been obvious to one skilled in the art to provide the servo motor disclosed in the Oku et al. patent for the motors in the Tung patent in view of the known use to turn a shaft.

Allowable Subject Matter

Claim 17 is considered to be allowable over the prior art of record.

US patents 4,874,358 and 5,151,368 teach away from the claimed invention in that the rate of rotation of the chamber about a first axis is matched by the rate of rotation about a second axis (col. 3, lines 27-37). There is no suggestion for providing independent and variable speed rotation of the devices.

Claims 4,5,8-10,12-13,16,17,20, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Redding whose telephone number is 571-272-1276. The examiner can normally be reached on Mon.-Fri. 6:00 - 3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "David A. Redding". The signature is written in a cursive, flowing style.

DAR